

FEB -6 1997

K963741

510(k) Summary

Device Proprietary Name: Leibinger® - Luhr® Small Craniomaxillofacial Bone Screw System

Device Common Name: Small Bone Screws

Classification Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories 888.3030

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Summary:

This submission describes a system of small bone screws. It is intended for use in internal fixation of small bones including the craniomaxillofacial skeleton secondary to trauma or for reconstruction. Screws are available in diameters ranging from 0.8 to 2.4 mm and lengths ranging from 2 mm to 28 mm. These devices are for single use only.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Howmedica Luhr® Fixation System (K761228, K882454, K913355, K935448); the Wurzburg® Bone Screws (K854886); the Steinhauser® Bone Screws (K862482) and the Howmedica Leibinger Forefoot Reconstruction System (K961485). The Luhr®, Wurzburg® and Steinhauser®, and Forefoot bone screws are intended for use as small bone screws in internal fixation procedures. The Forefoot screws are manufactured from Ti6Al4V. The basic operational principle is similar for each of these devices.